

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS,
MASSACHUSETTS CHAPTER OF AMERICAN
ACADEMY OF PEDIATRICS, INC.,
AMERICAN CANCER SOCIETY, INC.,
AMERICAN CANCER SOCIETY CANCER
ACTION NETWORK, INC., AMERICAN
HEART ASSOCIATION, INC., AMERICAN
LUNG ASSOCIATION, CAMPAIGN FOR
TOBACCO-FREE KIDS, TRUTH INITIATIVE
FOUNDATION D/B/A TRUTH INITIATIVE,
DR. TED KREMER, DR. JONATHAN
WINICKOFF and DR. LYNDA YOUNG,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION

Defendant.

Civil Action No. 16-cv-11985 (IT)

**FIRST SUPPLEMENT TO DEFENDANT’S LOCAL RULE 56.1 STATEMENT OF
UNDISPUTED MATERIAL FACTS**

Defendant wishes to apprise the Court of a matter that affects Defendant’s Local Rule 56.1 Statement of Undisputed Material Facts (ECF No. 35; filed 5/26/2017). In paragraphs 25 through 27 of that statement (addressing step (g)), Defendant explained the review and approval process that must be completed before the United States Food and Drug Administration (FDA) may undertake its initial quantitative study to assess warning statement text. FDA is currently awaiting the Office of Management and Budget’s (OMB’s) decision regarding approval of that proposed study.

FDA is similarly awaiting OMB’s decision regarding approval of the final qualitative test of images described in paragraph 23, pursuant to step (c).

This status affects FDA's prior estimates regarding when its research plan will be completed (previously, May 2019, per the final sentence of paragraph 29) and when a final rule may be submitted for publication (previously, July 2021, per the final sentence of paragraph 37), postponing both of those dates by approximately four months. That changes the estimated date for completion of research to September 2019 and submission of a final rule to November 2021.

Dated: January 22, 2018

Respectfully submitted,

ETHAN P. DAVIS
Deputy Assistant Attorney General

GUSTAV W. EYLER
Acting Director

ANDREW E. CLARK
Assistant Director
Consumer Protection Branch

/s/ Daniel K. Crane-Hirsch
DANIEL K. CRANE-HIRSCH, BBO #643302
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044-0386
Telephone: 202-616-8242
Fax: 202-514-8742
Daniel.Crane-Hirsch@usdoj.gov

Of Counsel:

ROBERT P. CHARROW
General Counsel
U.S. Department of Health and Human Services

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

PERHAM GORJI
Deputy Chief Counsel, Litigation

SUSAN WILLIAMS
Associate Chief Counsel
Office of the General Counsel
Food and Drug Division
10903 New Hampshire Avenue
White Oak 32, Room 4384
Silver Spring, MD 20993-0002

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as nonregistered participants on today's date.

/s/ Daniel K. Crane-Hirsch
January 22, 2018